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EXAMINER	
SWOPE, SHERIDAN	
ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,298	GILL ET AL.	
	Examiner	Art Unit	
	SHERIDAN SWOPE	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *11-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☒ Claim(s) *1,2 and 5-10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 April 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment of August 21, 2008, in response to the Action of April 21, 2008, is acknowledged. It is acknowledged that Claims 1 and 2 have been amended. Claims 1-42 are pending. Claims 11-42 were previously withdrawn from further consideration as being drawn to nonelected inventions. Claims 1-10 are hereby examined.

Priority

The priority date granted for the instant invention is April 1, 2004, the filing date of PCT/US04/10218, which disclosed the elected invention. It was previously noted that provisional application US 60/459,786 fails to disclose SEQ ID NO: 1 or 2. In response, applicants argue that the specification at pages, 8, 13, and 34-35 as well as Figure 1 disclose SCP1. It is acknowledged that pages 8 and 13 given some physical properties of the encoded protein, that pages 34-35 given a genomic sequence, and Figure 1 provides alignment of protein fragments. However, said evidence fails to provide the complete sequence for SEQ ID NO: 1 or 2. Therefore, the priority date granted for the instant invention is April 1, 2004.

Title

The title, as amended, is objected to because it is not descriptive of the elected invention, which is a polynucleotide encoding a phosphatase, not a kinase.

Drawings-Objections

Objection to Figure 1 for disclosing sequences that are not identified by a sequence identifier number (SEQ ID NO:), is maintained. It is acknowledged the legend to Figure 1 has been amended to recite SEQ ID NO: 2, 4, 6, 8, and 68; however, it is unclear which sequence has which SEQ ID NO:.

Specification-Objections

Objection to the specification for disclosing sequences that are not identified by a sequence identifier number (SEQ ID NO:), is maintained. Applicant is required to check the disclosure completely and to make corrections to identify all of the sequences disclosed therein by sequence identifier numbers.

Claims-Objections

Objection to Claims 1, 2, and 5-10, for reciting non-elected sequences, is maintained.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Rejection of Claims 1 and 5-10 under 35 U.S.C. 112, second paragraph, because the phrase "conservative substitutions" renders the claims indefinite, is maintained. Applicants argue that the specification defines "conservative substitutions", which is a well-known term in the art. This is not found to be persuasive. Although very common in the art, the term "conservative substitution" is vague and indefinite. For example, is a Gln/Glu substitution or an Asp/Asn substitution conservative? Are Ser/Tyr and Phe/Tyr conservative substitutions? Another situation that is indefinite is the classification of Gly and Ala; are these small polar residues, similar to Ser, Thr, Gln and Asn, or hydrophobic? Is His basic or hydrophobic? Are linear hydrophobic amino acids similar to aromatic hydrophobic amino acids? Is Cys a small polar amino acid or its own category? Is Tyr a polar amino acid or an aromatic amino acid? Lack of consensus on the answers to these questions causes the term "conservative substitution"

to be indefinite. The description of "conservative amino acid substitution" in paragraph [0073] is only exemplary and does not define the substitutions recited in Claims 1 and 5-10.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons. Claim 2 recites a series of nucleic acid molecules by GenBank Accession numbers. Said recitation renders the claim indefinite because the sequence disclosed by a GenBank Accession number can change over time. The skilled artisan would not know the metes and bounds of the recited invention.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Rejection of Claims 1 and 7-10 under 35 U.S.C. 112, first paragraph/enablement, for reasons explained in the prior action, is maintained. In support of their request that this rejection be withdrawn, Applicants provide the following arguments. The claims, as amended, recite both structure and function and, therefore, do not encompass any sequence having any biological activity. Methods of modification and screening are disclosed and known in the art.

These arguments are not found to be persuasive for the following reasons. It is acknowledged that methods to produce variants of a known sequence, such as site-specific mutagenesis, random mutagenesis, etc., are well-known to the skilled artisan. Methods for testing a protein for the ability to dephosphorylate RNA polymerase II or interact with

REST/NRSF are also known. However, producing variants having the desired activity requires that one know or be provided with guidance for the selection of which, of the essentially infinite number of variants, encompassed by the genus of any polynucleotide having at least 80% identity with SEQ ID NO: 1, have the activity. Without such guidance, one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has not been provided in the instant specification such that making any polynucleotide having at least 80% homology with SEQ ID NO: 1, have the desired activities would not constitute undue experimentation.

For these reasons and those explained in the prior action, rejection of Claims 1 and 7-10 under 35 U.S.C. 112, first paragraph/enablement, is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Rejection of Claims 1 and 5-10 under 35 U.S.C. 102(b), as being anticipated by Venter et al, 2002 for the reasons explained in the prior action, is maintained.

In support of their request that this rejection be withdrawn, Applicants provide the following arguments. Venter et al does not teach or suggest that their polynucleotide encodes a

protein having a recited activity. In order for a claim to be anticipated, the reference must teach each and every limitation. This argument is not found to be persuasive for the following reasons. It is not necessary for Venter et al to teach or suggest that their polynucleotide encodes a protein having an activity to dephosphorylate RNA polymerase II or to interact with REST/NRSF. Based on the fact that Venter's polynucleotide has 98.2% identity with SEQ ID NO: 1 and encodes a polypeptide having a single amino acid change, the skilled artisan would believe that, more likely than not, Venter's polynucleotide encodes a polypeptide having all of the properties of SEQ ID NO: 2 herein.

Since it is unclear what specific sequences are recited in Claim 2, analysis under 35 U.S.C. 102(b) and 103(a) is not possible at this time. Upon clarification as to what specific sequences are recited in Claim 2, any subsequent rejection under 35 U.S.C. 102(b) or 103(a) will not be considered a new grounds for rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Rejection of Claims 1, 3, and 5-10 under 35 U.S.C. 103(a) as being unpatentable over Cocks et al, 2003 in view of Meinnel et al, 1993, for the reasons explained in the prior action, is maintained.

In support of their request that this rejection be withdrawn, Applicants provide the following arguments. (i) Cocks et al teach a large number of sequences that may or may not

have start codons, stop signals, or activity. (ii) The polynucleotide of Cocks et al is ~2000 bp, of which lacks a start codon for methionine and only the first 781 align with SEQ ID NO: 1. (iii) There is no teaching in Cocks et al to suggest that their polynucleotide encodes a protein having an activity recited in Claim 1. (iv) Cocks et al should have been aware of the teachings of Meinnel et al and incorporated an N-terminal methionine. Failure to do indicates that Cocks et al has a sequence different from SEQ ID NO: 1. (v) Adding an N-terminal methionine may change the encoded protein's activity.

These arguments are not found to be persuasive for the following reasons. (i) The fact that Cocks et al teach a large number of sequences does not provide a prima facie case that the polynucleotide of Cocks et al does not encode a polypeptide having the desired activity. It is also noted that Cocks' polynucleotide has a TAG stop codon in the same position as SEQ ID NO: 1. (ii) It is acknowledged that polynucleotide of Cocks et al is ~2000 bp; said polynucleotide reads on Claims 1, 3, and 5-10, which recite polynucleotides encompassing SEQ ID NO: 1. (iii) As explained above for Venter et al, it is not necessary for Cocks et al to teach the activity of the polypeptide encoded by their sequence. The polynucleotide rendered obvious by Cocks et al and Meinnel et al comprises SEQ ID NO: 1 and, thus, inherently has the recited activity. It is also noted that a polynucleotide rendered obvious by Cocks et al and Meinnel et al is identical to SEQ ID NO: 1 (see below). (iv) Failure of Cocks et al to incorporate an N-terminal methionine does not provide a prima facie case that other skilled artisans would not be motivated to do so. It is acknowledged that Cocks et al has a sequence different from SEQ ID NO: 1; iff Cocks et al had the sequence set forth by SEQ ID NO: 1, this would be a rejection under 35 U.S.C. 102. (v) This argument is not relevant. The polynucleotide rendered obvious by

Cocks et al and Meinnel et al comprises to SEQ ID NO: 1 and, thus, inherently has the recited activity. It is also noted that a polynucleotide rendered obvious by Cocks et al and Meinnel et al is identical to SEQ ID NO: 1 (see below).

For these reasons and those explained in the prior action, rejection of Claims 1, 3, and 5-10 under 35 U.S.C. 103(a) as being unpatentable over Cocks et al, 2003 in view of Meinnel et al, 1993, is maintained.

Claim 4 is herein rejected under 35 U.S.C. 103(a) as being unpatentable over Cocks et al, 2003 in view of Meinnel et al, 1993. The teachings of Cocks et al and Meinnel et al are described above and in the prior action. The polynucleotide of Cocks et al has a stop codon at position ^{781}TAG^{783}, designating the end of the coding region. It would have been obvious to a person of ordinary skill in the art to combine the teachings of Cocks et al and Meinnel et al to modify the polynucleotide of Cocks et al to, in addition to incorporating an N-terminal methionine codon, to also terminate the polynucleotide at nucleotide G^{783}. Said polynucleotide would consist of SEQ ID NO: 1. Motivation to do so derives from the desire to reduce the size of the polynucleotide and vector used for protein expression, which is technically advantageous. The expectation of success is high, as methods for modifying polynucleotide are well-known in the art. Therefore, Claim 4 is herein rejected under 35 U.S.C. 103(a) as being unpatentable over Cocks et al, 2003 in view of Meinnel et al, 1993.

Allowable Subject Matter

No claims are allowable.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/
Primary Examiner, Art Unit 1652